

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 10-12 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751).

Oberlander discloses a sternal closure system for reapproximating left and right halves of a patient's longitudinally incised sternum during a surgical procedure in the thoracic cavity, the system comprising: a first, at least one anchor means (Fig. 2, ref. 20, left), adapted to be disposed inside the left half of the sternum; a second, at least one anchor means (Fig. 2, ref. 20, right), adapted to be disposed inside the right half of the sternum so as to facilitate separation of the left and right halves of the sternum when necessary; at least one fixing means (Fig. 1, ref. 30); an apparatus (Fig. 12, ref. 100) for simultaneous placing in the sternum said first, at least one anchor means, adapted for disposing within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum; a fixing apparatus (Fig. 12, ref. 120) for placing said fixing means adapted for rigidly connecting to one another said first, at least one anchor means, adapted to be disposed within the left half of sternum and said second, at least one anchor means, adapted to be disposed within the right

half of sternum; an apparatus (Fig. 6, ref. 32) for removing said fixing means when it is necessary to perform a post-operative surgical procedure in the thoracic cavity, whereby there is performed a rigid connection to one another of the left and the right halves of a patient's incised sternum during a surgical procedure within the thoracic cavity, facilitating separation of the left and right halves of sternum closed in this way, in case of post-operative emergency surgical procedures. The first, at least one anchor means, adapted to be disposed within the left half of the sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, are screws (Fig. 3, ref.21) having an external thread (Fig. 3, ref. 35) of one direction. The first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, have heads provided with means for grasping and rotating them by said apparatus for simultaneous placing of said anchor means (column 5, lines 56-60).

The heads of said first and said second anchor means are provided with means for their grasping by said apparatus for simultaneously placing said anchor means, said grasping means being generally shaped as grooves on the side surface of said heads (column 5, lines 60-67). The heads of said first and said second anchor means are provided with means for their rotation by said apparatus for simultaneously placing said anchor means, and these means for their rotation are generally cross-shaped slots (column 5, lines 60-67) on the end surface of said heads. The heads of said first and said second anchor means are provided with means for their rotation by said apparatus for simultaneous placing of said anchor means, and these means for rotation are

substantially shaped as hexahedral holes (column 5, lines 60-67) in the end face of said heads.

At least one fixing means (Fig. 1, ref. 30) adapted for rigidly connecting to one another said first, at least one anchor means, disposed within the left half of sternum to said second, at least one anchor means disposed within the right half of sternum is substantially shaped as a staple (Fig. 3, ref. 31) having a body (the middle portion of ref. 31) and at least two legs emerging from this body (the areas of ref. 31 closer to the screws) in a substantially perpendicular relationship (Fig. 13), whereby said staple is adapted for rigidly connecting said first, at least one anchor means, to said second, at least one anchor means.

Both said first, at least one anchor means, adapted to be disposed in the left half of the sternum, and said second, at least one anchor means, adapted to be disposed in the right half of the sternum, both have an inner axial passage (Fig. 2, ref. 25) adapted for disposing therein, substantially tightly, one of the corresponding legs of said staple.

The at least one fixing means is formed as a staple having a curved body (Fig. 3, ref. 31) and at least two slightly curved legs (Fig. 3, the portions of ref. 31 closer to the screws) for tightly disposing in a respective inner axial passage of said first, at least one anchor means adapted to be disposed in the left half of sternum, and said second, at least one anchor means adapted to be disposed in the right half of sternum. The first, at least one anchor means, adapted to be disposed within the left half of sternum, said second, at least one anchor means, adapted to be disposed within the

right half of sternum, and said at least one fixing means, are all made of FDA approved metal or alloy (column 6, lines 30-31), mainly of one of metal or alloy of the group, consisting of stainless steel (column 6, lines 30-31), titanium (column 6, lines 30-31), tantalum, alloys of titanium and tantalum.

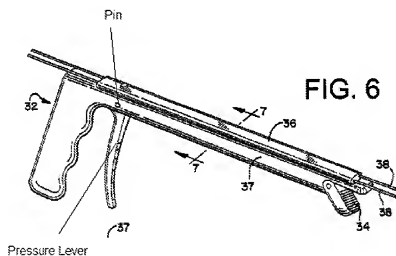
The first, at least one anchor means, adapted to be disposed within the left half of sternum, said second, at least one anchor means, adapted to be disposed within the right half of sternum, and said at least one fixing means, are all made from FDA approved biodegradable material (column 6, lines 18-30).

The apparatus for simultaneously placing in the sternum said first, at least one anchor means, adapted to be disposed within the left half of sternum, and said second, at least one anchor means, adapted to be disposed within the right half of sternum, comprises a frame means (Fig. 12, ref. 104) with vertical guides (Fig. 12, ref. 102).

The apparatus for simultaneously placing in the sternum said first, at least one anchor means adapted to be disposed within the left half of sternum, and said second, at least one anchor means adapted to be disposed within the right half of sternum, contains a frame means (Fig. 12, ref. 104) with two horizontal plates disposed in parallel relationship to each other (the top plate which can be seen in the drawing and the plate underneath the top plate) and at least one vertical guide (Fig. 12, ref. 102) rigidly connected at least with one of these plates.

Oberlander further discloses an apparatus for removing said fixing means when it is necessary to perform a post-operative surgical procedure within the thoracic cavity containing: a hollow body (Fig. 6, ref. 36 and 37) (column 7, lines 57-58) provided with a

handle (near ref. 32) extending therefrom, and in its lower part with a bifurcated stop (the bottom portions of the two separate halves of the handle); a grasping member (Fig. 8, ref. 34) movably disposed within this body; a pressure lever (Fig. 6 below) pivotally mounted on a pin (Fig. 6 below) within the upper part of the hollow body, this pressure lever has a handle extending substantially in the same direction as said handle of hollow body (Fig. 6, ref. 36 and 37) (column 7, lines 57-58) and a free end located within the hollow body and operatively connected to said spring-loaded grasping member. There must be a connection inside that connects the handle to the grasping portion; otherwise there would be no way to operate the grasper with the handle.



Oberlander discloses the claimed invention except for the legs each being adapted for insertion in a respective one of said axial passages and the legs of said

rigid fixing means being adapted for subsequent extraction from the respective axial passages and for re-insertion therein; and a fastener having two legs each being adapted for repeated insertion and withdrawal from a respective one of said inner axial passages. Oberlander does, however disclose a fixing means (Fig. 1, ref. 30) which connects two anchors (Fig. 2, ref. 20, left).

Fenton, Jr. discloses a sternal closure system (Fig. 10) that comprises two anchor means (Fig. 10, refs. 12) having axial passages (Fig. 10, ref. 50) and at least one rigid (column 5, lines 60-67 and column 6, lines 1-6) fixing means (or fastener) (Fig. 10, ref. 60) comprising two legs (Fig. 10) the legs being adapted for subsequent extraction from the respective axial passages and for reinsertion therein (Fig. 10). The fixing means connects the two anchors (Fig. 10). Furthermore, the fixing means is attached to the anchor means through application of energy (column 6, lines 33-38), which allows the fixing means to be set to a desired tension and/or create a desired size for the tissue capture region, thus adding more adjustability to the device (column 6, lines 38-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the fixing means of Oberlander with the fixing means as taught by Fenton, Jr., in order to achieve the predictable result of connecting anchors. Furthermore, the Fenton mechanism allows the fixing means to be set to a desired tension and/or create a desired size for the tissue capture region, thus adding more adjustability to the device (column 6, lines 38-41).

With regard to claim 3, Oberlander in view of Fenton, Jr. disclose the claimed invention except for the screws having an external thread of different directions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the screws having an external thread of different directions, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claims 1-8 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751) in view of Sasaki et al. (US Pat. 5,735,183).

Oberlander discloses the claimed invention except for the apparatus for simultaneously placing in the sternum first, at least one anchor means, and said second, at least one anchor means, comprising: a power means to generate a torque; a means for transmitting torque simultaneously to said first and said second anchor means; a means for searching and grasping simultaneously said first and said second anchor means; a means for retaining and simultaneously delivering said first and said second anchor means to said means for their searching and grasping. The power means for generating a torque comprises one of the means of a group including an electric, pneumatic or hydraulic engine. The means for transmitting torque simultaneously to said first and said second anchor means is generally a gear box having one drive shaft and at least two driven shafts. On the driven shafts of said

gearbox there are mounted spring-loaded heads forming said means for searching and grasping simultaneously said first and said second anchor means.

Sasaki et al. disclose an apparatus comprising: a power means to generate a torque (column 5, lines 56-60); a means for transmitting torque (column 5, lines 57-60); a means for searching and grasping (Fig. 13a, the areas attached to spring 64 and attached to the unlabeled spring on the opposite side of the device); a means for retaining and delivering said first and said second anchor means to said means for their searching and grasping (Fig. 13a, ref. 3). The power means for generating a torque comprises one of the means of a group including an electric, pneumatic or hydraulic engine (column 1, lines 14) (column 5, lines 56-60). The means for transmitting torque to said first and said second anchor means is generally a gear box having one drive shaft (column 5, lines 57-60). On the driven shaft (Fig. 13c, ref. 7) of said gear box there are mounted spring-loaded heads (Fig. 13a, the areas attached to spring 64 and attached to the unlabeled spring on the opposite side of the device) forming said means for searching and grasping said first and said second anchor means. The apparatus is used as a power screwdriver (column 1, lines 6-7).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the apparatus for simultaneous placing of Oberlander with the power means to generate a torque; a means for transmitting torque; a means for searching and grasping; a means for retaining and delivering said first and said second anchor means to said means for their searching and grasping; the power means for generating a torque comprising one of the means of a group including an

electric, pneumatic or hydraulic engine; the means for transmitting torque to said first and said second anchor means is generally a gear box having one drive shaft; on the driven shaft of said gear box there are mounted spring-loaded heads forming said means for searching and grasping said first and said second anchor means of Sasaki et al. The apparatus of Oberlander could then be used as a power screwdriver Sasaki et al., column 1, lines 6-7), and the apparatus could then be used to engage the screwdriver ready heads of the screws of Oberlander (Oberlander, column 5, lines 56-68).

Claims 1-8 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751) in view of Sasaki et al. (US Pat. 5,735,183) in view of Runck et al. (US Pat. 3,832,139).

Oberlander in view of Sasaki et al. discloses the claimed invention except for the means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping contains two spring-loaded rotary drums disposed between the plates within said frame means.

Runck et al. discloses means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping contains two spring-loaded (column 5, lines 50-54) rotary drums (Fig. 4, ref. 80 and 81) disposed between the plates within said frame means (Fig. 4, ref. 82), for permitting insertion and withdrawal of a pair of plungers (column 4, lines 57-59).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping of Oberlander in view of Sasaki et al. with the two spring-loaded rotary drums disposed between the plates within said frame means of Runck et al., in order to permit insertion and withdrawal of a pair of plungers (column 4, lines 57-59), which could be used to deliver the anchors of Oberlander (Fig. 2, ref. 20) to tissue (Oberlander, abstract, lines 3-5).

Claims 1-8,10-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751) in view of Sasaki et al. (US Pat. 5,735,183) in view of Runck et al. (US Pat. 3,832,139).

Oberlander in view of Sasaki et al. discloses the claimed invention except for the means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping comprising a spring-loaded cartridge means disposed within said frame means.

Runck discloses the means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping comprising a spring-loaded (column 5, lines 50-54) cartridge means (Fig. 4, ref. 80, 81, 84, 85, 87, and 86) disposed within said frame means (Fig. 4, ref. 82),

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the means for retaining and simultaneous delivering of said first and said second anchor means to said means for their searching and grasping of Oberlander in view of Sasaki et al. with the spring-loaded cartridge means disposed within said frame means of Runck et al., in order to permit insertion and withdrawal of a pair of plungers (column 4, lines 57-59), which could be used to deliver the anchors of Oberlander (Fig. 2, ref. 20) to tissue (Oberlander, abstract, lines 3-5).

Claims 1-8, 10-12 and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751) in view of Bone (US Pat. 3,875,648).

Oberlander discloses the claimed invention except for the fixing apparatus as described in claims 22-30.

Bone discloses a fixing apparatus for placing and removing said fixing means adapted for rigidly securing to one another said first, at least one anchor means, adapted to be disposed within the left half of sternum and said second, at least one anchor means, adapted to be disposed within the right half of sternum comprising: at least two levers, first and second (Fig. 27, below) each of them having a proximal end and a distal end, these levers being pivotally connected to one another (column 3, lines 21-22) (column 3, lines 27-29) and provided with handles at their distal ends (Fig. 27, below) and means for grasping heads of anchor means at their proximal ends (Fig. 27,

below); at least one third lever (Fig. 42 below) pivotally connected to said first lever or said second lever and provided with a handle at its distal end (Fig. 42 below), and at its proximal end with a means for delivering the fixing means inside said first and said second anchor means (Fig. 42 below), formed substantially as a pusher (Fig. 48, ref. 242, 243 and 186) (column 11, lines 22-28); a means for retaining and by the piece delivering of fixing means (Fig. 42 below), formed substantially as a movable spring-loaded die (Fig. 48, ref. 243, 241 and 210) with slots (Fig. 41. ref. 198) for disposing fixing means.

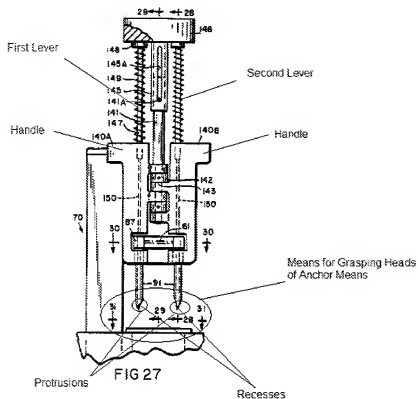
The means for grasping the heads of anchor means are formed as two protrusions facing one another (Fig. 27 below), one of them being disposed at the proximal end of first lever, and the second at the proximal end of the second lever, and these protrusions have, at their free ends, recesses (Fig. 27 below) matching in shape the grooves on the side surface of heads of said anchor means. The fixing apparatus comprises at least one third lever (Fig. 42 below) pivotally connected to said first lever or with said second lever (column 10, lines 44-45) and spring-loaded relative (Fig. 48, ref. 243, 241 and 210) to this first or second lever, said third lever being provided with a handle (Fig. 42 below) at its distal end, and at its proximal end with a means for delivering the fixing means inside said first and said second anchor means (Fig. 42 below), which is shaped substantially as a pusher (Fig. 48, ref. 242, 243 and 186) (column 11, lines 22-28). The fixing apparatus has a means for retaining and by the piece, delivering of fixing means (Fig. 42 below), comprising generally a movable spring-loaded die (Fig. 48, ref. 243, 241 and 210) with slots for disposing these fixing

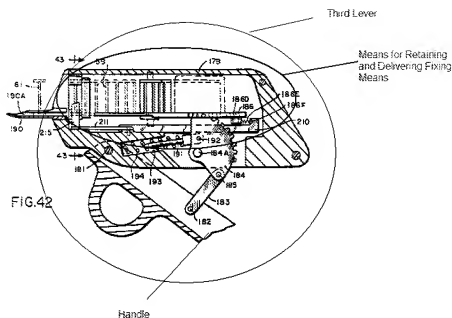
means, this die being adapted to perform stepping linear movement in a guide, which is rigidly connected to said first lever or to said second lever of said fixing apparatus.

The fixing apparatus for placing said fixing means adapted for rigidly connecting together said first, at least one anchor means adapted to be disposed within the left half of sternum and said second, at least one anchor means adapted to be disposed within the right half of sternum, this fixing apparatus comprising: at least two levers, the first and the second (Fig. 27 below), each of them having a proximal end and a distal end, these levers are pivotally connected to one another (column 3, lines 21-22) (column 3, lines 27-29) and provided with handles at their distal ends (Fig. 27 below), as well as with means for grasping the heads of anchor means at their proximal ends (Fig. 27 below); at least one third lever (Fig. 42 below) pivotally (column 10, lines 44-45) connected to a bearing plate (Fig. 42, ref. 179) rigidly secured on said first lever or said second lever, this third lever is provided with a handle at its free end (Fig. 42 below), and pivotally connected by its middle to the means for delivering the fixing means inside said first and said second anchor means formed substantially as a pusher (Fig. 48, ref. 242, 243 and 186) (column 11, lines 22-28); a means for retaining and by the piece delivering of fixing means (Fig. 42 below) formed substantially as a cartridge enclosing spring-loaded fixing means located right up to one another.

The fixing apparatus contains at least two levers, the first and the second (Fig. 27 below), each of them having a proximal end and a distal end, these levers are pivotally connected to one another (column 3, lines 21-22) (column 3, lines 27-29) and provided with handles at their distal ends (Fig. 27 below), means for mutually fixing the

handles when brought together, as well as by means for grasping the heads of anchor means at their proximal ends. The button and button holes can be considered the means for mutually fixing the handles when brought together, since, when the levers are pivoted together, they could be held in that position by the button once the levers are placed through the button holes (column 10, lines 27-33). If the levers are held in position, then so are the handles, which are attached to the levers (Fig. 27, below). The means for grasping the heads of anchor means are configured as two protrusions (Fig. 27 below) facing one another, one of which is disposed at the proximal end of the first lever, and the second at the proximal end of the second lever, and these protrusions have at their free ends recesses (Fig. 27 below) matching in shape the grooves on the side surface of heads of said anchor means. The fixing apparatus contains a single unit including at least one third lever (Fig. 42 below), a means for retaining and by the piece delivery of fixing means (Fig. 42 below) formed substantially as a cartridge, and a means for delivering a fixing means inside said first and said second anchor means formed substantially as a pusher (Fig. 42 below); this single unit is pivotally (column 10, lines 44-45) connected to the bearing plate rigidly mounted on said first lever or said second lever and is capable of folding back in the vertical plane to provide viewing of said means for grasping the anchor means or returning into operative position with simultaneous rigid fixing of the cartridge at the proximal ends of said first and second levers of the fixing apparatus.





Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oberlander (US Pat. 6,554,852 B1) in view of Fenton, Jr. (US Pat. 6,056,751) in view of Bone (US Pat. 3,875,648).

Oberlander discloses the claimed invention except for the grasping member being spring-loaded.

Bone discloses an apparatus that is spring-loaded (Fig. 48, ref. 233), the spring being positioned to return a lever to an original position once an external force is removed (column 12, lines 10-13).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the grasping member of Oberlander with a

spring to make it spring loaded, in order to return the grasping member to an original position once an external force is removed (column 12, lines 10-13).

Response to Arguments

Applicant's arguments filed 02/26/2008 have been fully considered but they are not persuasive.

With regard to Applicant's argument directed toward the phrase "sternal closure system" the examiner notes that this terminology does not impart any structural limitations on the claims and is thus being interpreted by the examiner as a functional limitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). In this case, the devices of Oberlander and Fenton, Jr. can be used in a process of sternal closure.

With regard to the rigidity of the fixing mean, Fenton, Jr. discloses that the fixing means is rigid (column 5, lines 60-67 and column 6, lines 1-6). As this portion is the portion being combined with the Oberlander reference, the combination comprises a rigid fixing means.

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In *re Nomiya*, 184

USPQ 607 (CCPA 1975). Whether the two systems are being used for a "sternal closure system" is not the relevant point, but rather whether someone of ordinary skill in the art would have been motivated to combine these two specific references in order to arrive at the claimed invention. In this case the devices are analogous to one another both structurally and functionally. Furthermore, it would have been obvious to a person having ordinary skill to have substituted the functionally equivalent "fixing means" for one another in order to achieve the predictable result of connecting the anchor means. Furthermore, though both fixing means are disclosed as being used to connect the fixing means Fenton, Jr. discloses that the fixing means is, at least initially, non-integrally attached to the anchor means, which adds more adjustability to the device (column 6, lines 38-41). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the fixing means of Oberlander with the fixing means of Fenton, Jr.

With regard to Applicant's argument that the fixing means is not releasably attached to the anchor means the examiner respectfully disagrees. Initially, prior to fusion the fixing means as taught by Fenton, Jr. is not directly attached to the anchors, and is thus releasable. Also, prior to the fusion process, the fixing means (or fastener) is capable of repeatedly being inserted and removed from the passages as recited in new claim 36. Secondly, even after being fused, the fixing means can be removed if one so chose. The portion where the fusion takes place could either be melted again or the fixing means could be cut from the anchors.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JERRY CUMBERLEDGE** whose telephone number is (571)272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. C./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733